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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
05/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,123	GRAVETT ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *154,163-168,241-244 and 246-259* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *154,163-168,241-244 & 246-259* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Remarks filed on 03/12/2009.

Claims 154, 163-168, 243, 246, 251 and 253 have been amended.

Claims 155-162 and 169-172 have been cancelled.

Claims 256-259 have been added.

Claims 154, 163-168, 241-244 and 246-259 are pending in the instant application.

Claim Objection

Claim 246 objected is withdrawn in view of applicant's amendment to claims.

Claim Rejections - 35 USC § 112

Claims 154-172,241-244 and 246-255 are rejected under 35 U.S.C. 112, first paragraph, **are withdrawn** in view of Applicant's amendment to claims.

Double Patenting

Claims 154, 155, 162,241-244 and 247-255 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 18-21,89-91,93-95, 108, 110, and 131-141 of copending Application No 10/749,117 **are withdrawn** in view of abandonment of copending application.

Claim Rejections - 35 USC § 102

1. Claims 154-157, 161,165, 166,168, 172, 241-246 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. (US 200110055615 A1) **are withdrawn** in view Applicant's amendment to claims.

Claims 154, 155, 161,169-172, 241-246 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhee et al. (US 6,166,130) **are withdrawn** in view of Applicant's amendment to claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 154, 163-168, 241-244 and 246-259 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (US 2001/0055615) in view of Rhee et al (US 6,166,130) and Greenwald et al (US 5,965,566).

Wallace discloses a method of tissue repair and tissue related applications comprising a sulfhydryl reactive PEG compounds and succinimidyl reactive PEG compounds such as sulfhydryl-PEG/SG- PEG; sulfhydryl-PEG/SG-PEG/methylated (0017-0020) suitable for use in tissue engineering application such as, tissue sealants, in tissue augmentation, in tissue repair, as hemostatic agent in the prevention of

surgical adhesion, in providing surface modifications, and in drug delivery application (0066). Preferably, composition comprises four or 12 functional groups to ensure sufficient reactivity for formation of a three dimensional polymer matrix. The method includes applying the composition onto the damaged tissue or organ either by spraying or by applying previously admixed components to form a hydrogel on the tissue surface (which would read on formation of covalent bonds with the biological tissue, 0005 and 0071). The polymeric composition comprising biologically active substance such as antibiotics, antineoplastic agents, antiangiogenic agents, and the like, suited for use in a variety of biological tissue related applications when rapid adhesion to the tissue and gel formation is desired (abstract). The tissue treatment composition can be used for reducing the formation of adhesions after a surgical procedure in a patient by applying onto the damaged tissue or organ either by spraying or by applying composition, to form a hydrogel on the tissue surface. The medical procedures include gynecological, abdominal, neurosurgical, cardiac, and orthopedic indications (0071). And further, composition can be applied as coatings to implants to affect the surface properties of implants or to help adhere implants to tissue surfaces e.g. catheters or breast implants to reduce or stop excessive fibrosis (which would read on biological tissue that has undergone surgery to excise a tumor 0075).

Wallace discloses tissue treatment composition comprising, synthetic polymer. Suitable synthetic hydrophilic polymer includes, polyalkylene oxide, such as polyethylene oxide and multifunctionally activated polyalkylene oxides, such as polyethylene glycol, (0039 and 0040). And also chain extenders or linking groups like

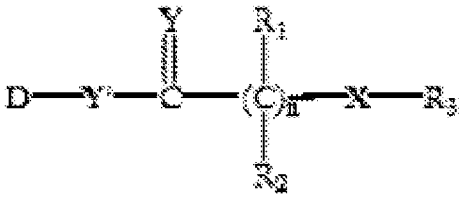
alpha hydroxyl acids such as lactic acid and glycolic acid; poly (lactones) can be incorporated into one or both of the multi functionally activated polymeric composition (0047 and 0048). In an alternative embodiment, component can be mixed together in a single aqueous medium in which they are both unreactive, i.e., such as in a low pH buffer. Thereafter, they can be sprayed onto the tissue site along with a high pH buffer, after which they will rapidly react and form a gel (0059).

Wallace fails to disclose a drug such as cell cycle inhibitor (taxane) in the synthetic polymer for affecting biological process in vivo.

Rhee discloses a method for using the crosslinked polymeric compositions to prevent the formation of surgical adhesions, as bioadhesives for tissue augmentation and also to coat a surface of a synthetic implant (see abstract). The crosslinked polymer composition comprise a synthetic polymer containing multiple nucleophilic and two or more electrophilic groups and/or biologically active agents such as growth factors may be delivered from the composition to a local tissue site in order to facilitate tissue healing and regeneration (col. 15, line 34-40). Preferred multifunctionally activated polyethylene glycols for the use in the composition includes polyethylene glycols containing succinimidyl groups (see column 9, line 23-26). The backbone of each polymer is preferably a polyalkylene oxide, particularly ethylene oxide, propylene oxide, and mixture thereof. Examples of difunctional alkylene oxides can be represented by: X-polymer-X and Y-polymer-Y. The required functional groups X or Y is commonly coupled to the polymer backbone by a linking group "Q" (wherein Q = -O-$(CH2)_n$-). An additional group, represented as "D", can be inserted between the polymer and the

linking group to increase degradation of the crosslinked polymer composition in vivo, for e.g. for use in drug delivery application. The biodegradable groups "D" includes lactide, glycolide, poly (alpha-hydroxy acid) and various di- or tripeptides (col. 5).

Greenwald discloses method of treatment of various medical conditions in mammal comprising a prodrug composition of biologically active compound (taxane derivatives) attached to the polymer of the formula:



Wherein: D is a residue of a biologically active moiety; X is an electron withdrawn group; Y and Y' are independently O or S; R1 and R2 are independently selected from groups consisting of H, C_{1-6} alkyls, aryls, substituted aryls, aralkyls, heteroalkyls, substituted heteroalkyls and substituted C_{1-6} alkyls: R3 is a polyalkylene oxide (see abstract). And the biologically active compounds (taxol or paclitaxel), have been found to be effective anti-cancer agents and has been used systemically with efficacy in treating several human tumors, including ovarian, breast, and non-small cell lung cancer. And compositions (paclitaxel 2'PEG ester) are useful for treating neoplastic

disease, reducing tumor burden, preventing metastasis of neoplasms and preventing recurrences of tumor/neoplastic growth in mammals.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate paclitaxel, loaded in the synthetic polymer comprising poly(alkylene oxide) functionalized with multiple activated groups as taught by Wallace. One of ordinary skill in the art would have been motivated to make these modifications because Wallace teaches that the composition comprising synthetic polymers and biologically active substances are useful as tissue sealants, in tissue repair, in providing surface modifications, and in drug/cell delivery applications. Therefore, one of ordinary skill in the art would have had a reasonable expectation because both Wallace and cited reference teaches a composition that can be used in same field of endeavor such as method of treating neoplastic disease by applying the composition onto the damaged tissue or organ either by (spraying or by applying), thereby reducing tumor burden, preventing metastasis of neoplasms and preventing recurrences of tumor/or neoplastic growth in the mammals.

Response to Arguments

Applicant's arguments filed on 03/12/2009 have been fully considered but they are not persuasive.

Applicants asserts that Wallace and Rhee reference does not disclose or suggest applying a composition of essentially single synthetic polymer and a drug to biological tissue that has undergone surgery to excise tumor.

This argument is not persuasive since the instant claim recites "a synthetic polymer and a drug, the synthetic polymer comprising poly(alkylene oxide) functionalized with multiple activated groups Y" and Y is reactive with X. Wallace in one embodiment teaches that when only one of the reactive compounds comprises a polymer core, the other reactive compound is a multifunctionally active small organic molecule. Such compound includes the di-functional di-succinimidyl esters and di-maleimidyl compounds (0008). According to Wallace, two polymers were mixed to form single polymer, wherein the single polymer has multiple functional groups to react with X. Instant claims neither excludes nor recite how the single polymer comprising PEO is formed. Thus Wallace reference still meets the requirement of the instant claims.

The instant claims neither exclude nor recite how the single polymer comprising PEO is formed. And further Rhee discloses that multifunctionally activated synthetic polymers for use have been chemically modified (for example, PEG can be derivatized to form functionally activated PEG propion aldehdye, the tetrafunctionally activated form Fig 10; SG-PEG and SE-PEG shown in Figs 4-7). Thus Rhee reference still meets the requirement of the instant claims.

Applicant also asserts that Greenwald reference does not teach the claimed features that are missing in Wallace. This argument is not persuasive since this reference is combined for its teachings of knowledge in the art of compositions useful for treating neoplastic disease, reducing tumor burden, preventing metastasis of neoplasms and preventing recurrences of tumor/neoplastic growths in mammals. Given both the prior art and the claims in their present form, their broadest reasonable

interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 & 2123.

Conclusion

1. No claims are allowed at this time.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr